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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/017,715	02/03/1998	HONGJUN JI	1488.0810003	8739

7590

11/04/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/017,715

Applicant(s)
Ji et al

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-42, 44-47, 50, 51, 53, and 57-77 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-42, 46, 47, 50, 51, and 53 is/are allowed.
- 6) ☒ Claim(s) 44, 45, and 57-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 27 6) ☐ Other:

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Response to Amendment

1. Claims 43 and 78 have been canceled. Claims 44-47, 50, 51, 53, 57-59, 71, 72, 76, 77 have been amended. Claim 48 was not amended as it was canceled with the amendment filed August 14, 2001. Claims 16-42, 44-47, 50, 51, 53, 57-77 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

3. The rejection of claims 43, 46, 50, 51, 53 and 78 under 35 U.S.C. 102(b) as being anticipated by Adams et al (WO 93/16178) as evidenced by Accession Number AAQ61421 is withdrawn in light of applicants amendments.
4. The rejection of claims 43, 46, 50, 51, 53, 78 and 47 under 35 U.S.C. 103(a) as being unpatentable over Adams et al (WO 93/16'78) in view of Sambrook et al (Molecular Cloning, A Laboratory Manual, 2nd Edition 1989, pages 10.27-10.28) is withdrawn in light of applicants amendments.

Claim Rejections Maintained

5. The rejection of claims 44, 45 and 57-77 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Is maintained for reasons of record.

Applicant has amended claims 44, 45, and 57-59 to read on a polynucleotide "consisting of at least" the disclosed polynucleotides in order to overcome this rejection. This has been considered but not found persuasive. Claims drawn to a polynucleotide consisting of at least "X" contiguous nucleotides of a SEQ ID NO: Z, or encoding a polypeptide consisting of at least Y amino acids of SEQ ID NO: W are considered to have "open language" in that they are not limited by the recited SEQ ID NO, but can be any polynucleotide consisting of at least X contiguous polynucleotides or any polynucleotide encoding the polypeptide fragments. Amendment of claims 44 and 45 to recite "an isolated polynucleotide fragment of SEQ ID NO:1, wherein said fragment consists of at least 100 or 250 contiguous polynucleotides of SEQ ID NO:1" would obviate this rejection over claims 44-47. Amendment of claim 57 to recite "an isolated polynucleotide encoding a fragment of SEQ ID NO:2, wherein said fragment consists of at least amino acids 94-107 of SEQ ID NO:2 or amino acids 120-127 of SEQ ID NO:2" would obviate this rejection over claims 57-59.

Applicant has amended claims 71, 72, 76 and 77 to recite the limitation "wherein said polynucleotide encodes a polypeptide which binds an antibody with specificity for the polypeptide consisting of amino acids 1-127 of SEQ ID NO:2. Applicant argues that it is a mis-interpretation of the written description requirement to require that the claimed variants encode fully functional BCSG-1 in order to have a function. This has been considered but not found persuasive.

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Applicant has misinterpreted the examiners explanation of the written description requirement. To satisfy the written description requirement, a statement of an "essential feature" of the invention is necessary. Binding to an antibody with specificity for any epitope of SEQ ID NO:2 is not an essential feature of the claimed variant polynucleotides, and further, the specification does not disclose an epitope of SEQ ID NO:2 that would be an antigenic site on SEQ ID NO:2 useful for the diagnosis of breast cancer. Over expression of the claimed polynucleotides are diagnostic for breast cancer. Amendment of claims 71, 72, 76 and 77 to recite "wherein said polynucleotide is over expressed in breast cancer" in place of binding to an antibody with specificity for the polypeptide consisting of amino acids 1-127 of SEQ ID NO:2 would incorporate the essential feature of the claimed invention into the claims for variant polynucleotides.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

November 4, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER